IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT WHEELING

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No. 1:22-CV-35-JPB

STIPULATION OF LIABILITY

Plaintiffs AstraZeneca AB and AstraZeneca Pharmaceuticals LP (collectively "Plaintiffs") and Defendants Mylan Pharmaceuticals Inc. and Kindeva Drug Delivery L.P. (collectively "Defendants"), by and through their respective counsel, have agreed to the following stipulation, subject to the approval of the Court.

WHEREAS, Plaintiffs filed this action for infringement of U.S. Patent No. 11,311,558 (the "'558 patent") alleging that (1) the filing of Defendants' Abbreviated New Drug Application, ANDA No. 211699 ("Mylan's ANDA"), to the U.S. Food and Drug Administration for a generic version of Symbicort® inhalation products ("Mylan's ANDA Products") constituted infringement of the '558 patent under 35 U.S.C. § 271(e)(2)(A), and (2) the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the '558 patent under 35 U.S.C. §§ 271(a), (b), (c), (f), and/or (g);

WHEREAS, Plaintiffs originally asserted infringement of specific claims of the '558 patent, specifically, claims 1-7, 12 and 13 of the '558 patent (the "Originally Asserted Claims");

WHEREAS, Plaintiffs subsequently narrowed the Originally Asserted Claims that they intended to assert at trial to a subset of the Originally Asserted Claims, specifically, claims 1, 3, 4, 7, and 12 of the '558 patent (the "Asserted Claims");

WHEREAS, for purposes of streamlining this litigation, Plaintiffs do not currently allege that (1) the filing of Mylan's ANDA infringes claims 2, 5-6, 8-11 and/or 13 of the '558 patent (the "Non-Asserted Claims"), or (2) the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Products would infringe the Non-Asserted Claims under 35 U.S.C. § 271(a), (b), (c), (f), and/or (g).

WHEREAS, Defendants have asserted defenses and Counterclaims that the Asserted Claims are invalid, claim 12 of the '558 patent is not infringed by Mylan's ANDA Products, and

that there is no act of infringement under 35 U.S.C. § 271(e)(2);

WHEREAS, on November 23, 2022, the Court issued a Memorandum Opinion and Order (ECF No. 204) (the "Claim Construction Order"), construing the term "pharmaceutical composition," as recited by all claims of the '558 patent, to, *inter alia*, "not include a functional stability requirement;" and

WHEREAS, in the Claim Construction Order the Court also construed the term "about 0.001% w/w," as recited by claim 12 of the '558 patent, to mean "approximately" 0.001% w/w;

WHEREAS, Defendants filed a Motion for Partial Summary Judgment that the filing of Mylan's ANDA was not an act of infringement under 35 U.S.C. § 271(e)(2), because, *inter alia*, Mylan's ANDA was finally approved before the issuance of the '558 patent (ECF Nos. 156-157) (the "Motion"), and AstraZeneca opposed the motion (ECF No. 165), and Mylan replied in support of the Motion (ECF Nos. 178-79);

WHEREAS, the Court issued its Memorandum Opinion and Order (ECF No. 223) ("Summary Judgment Opinion") concluding that "Mylan supplemented the ANDA by submitting two 'Prior Approval Supplements' after the patent-at-suit issued. Such an act is a qualifying act of infringement under § 271(e)(2)(A). Clearly there is a patent in place and clearly an ANDA infringes it." Summary Judgment Opinion at 20.

WHEREAS, Defendants respectfully disagree with the Court's construction of the "pharmaceutical composition" and "about 0.001% w/w" terms in the Claim Construction Order and the Court's Summary Judgment Opinion finding that Mylan's ANDA infringes under 35 U.S.C. § 271(e)(2), and intend to expeditiously appeal the Claim Construction Order and the Summary Judgment Order, and the Court's ultimate final judgment to the U.S. Court of Appeals for the Federal Circuit, as the '558 patent expires in less than two months;

WHEREAS, in light of the above, the only remaining liability issue relates to Defendants' defense and Counterclaim that the '558 patent is invalid; and

WHEREAS, the parties have met and conferred to resolve the remaining liability issue.

NOW THEREFORE, the parties stipulate and agree as follows:

1. Defendants consent to the entry of judgment in this action that the Asserted Claims are not invalid based on the Court's construction of the term "pharmaceutical composition." If Defendants appeal the Court's claim construction and if, in Defendants' appeal, the U.S. Court of Appeals for the Federal Circuit reverses or modifies the Court's construction of "pharmaceutical composition" in a manner that vacates or reverses the judgment of this Court, then Defendants may request, and Plaintiffs will not contest, vacatur of this stipulation of validity of the Asserted Claims. If this stipulated order is dismissed or vacated, Plaintiffs reserve all rights to assert the Asserted Claims.

2. Defendants consent to the entry of judgment in this action that the Asserted Claims are infringed under 35 U.S.C. § 271(e)(2) based on the Court's Summary Judgment Order, which Defendants intend to appeal. If on appeal, the Court's finding of infringement under 35 U.S.C. § 271(e)(2) is reversed, mooted or vacated by the U.S. Court of Appeals for the Federal Circuit, then Defendants may request, and Plaintiffs will not contest, vacatur of this stipulation of infringement of the Asserted Claims.

3. This Joint Stipulation is not an agreement to the proper scope of relief, including an injunction or order, if any, under 35 U.S.C. § 271(e)(4), the Court' general equitable power, or that Plaintiffs are entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A), and Defendants reserve all rights to dispute or appeal, if necessary, any relief entered in this case. For the avoidance of doubt, this stipulation alone does not entitle Plaintiffs to any injunctive relief or order, including

pursuant to 35 U.S.C. §§ 271(e)(4)(A) or (B).

4. Notwithstanding the above, upon the entry of a final judgment in this case, Defendants consent to be subject to an injunction under 35 U.S.C. § 283 enjoining Defendants, their affiliates and subsidiaries, and all persons and entities acting in concert with Defendants from commercially manufacturing, offering for sale, or selling Mylan's ANDA Products within the United States, or importing Mylan's ANDA Products into the United States, until the expiration of the '558 patent on January 29, 2023.

5. Defendants specifically reserve the right to appeal any final judgment entered by this Court.

6. Should this Stipulation be vacated, nothing herein shall be construed as a waiver by Plaintiffs or Defendants of any claim or defense with the regard to the Asserted Claims.

7. Defendants and Plaintiffs reserve all other claims and defenses.

Dated: December 12, 2022

Respectfully submitted,

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IT IS SO ORDERED this 12th day of December, 2022.

United States District Judge